DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 31, 2016

Boston Scientific Corporation
Endoscopy
Janis Taranto
Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, MA 01752

Re: K110833
Trade/Device Name: CRE™ Balloon Dilation Catheter
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FDT, FDF, KNQ
Dated (Date on orig SE ltr): March 22, 2011
Received (Date on orig SE ltr): March 25, 2011

Dear Janis Taranto:

This letter corrects our substantially equivalent letter of April 20, 2011

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known):	~~To Be Determined~~ K110833
Device Name:	CRE™ Balloon Dilatation Catheter
Indications for Use:	Indicated for use in adult and adolescent populations to endoscopically dilate strictures of the alimentary tract. The recommended application is printed on the package label referring to any combination of esophageal, pyloric and colonic dilatation.

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K110833

510(k) SUMMARY

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Telephone: 508-683-4560
Fax: 508-683-5939

Contact: Janis F. Taranto, M.S., RAC
Regulatory Affairs Specialist
Date Prepared: March 21, 2011

APR 2 0 2011

2. Proposed Device:

Trade Name: CRE™ Balloon Dilatation Catheter
Classification Name: 1) Endoscope and/or accessories 2) Dilator, esophageal
Regulation Number: 1) 876.1500 2) 876.5365
Product Code: 1) KOG, 2) KNQ
Classification: Class II

3. Predicate Device:

K974788
Trade Name: CRE™ Balloon Dilatation Catheter
Classification Name: CRE™ Balloon Dilatation Catheter Regulation Number: 1) 876.1500 2) 876.5365
Product Code: 1) KOG, 2) KNQ
Classification: Class II

4. Proposed Device Description:

The proposed CRE™ Balloon Dilatation Catheter is capable of 3 distinct and progressively larger size diameters via controlled radial expansion. It is designed to pass through the working channel of an endoscope and accept a 0.035 in (0.89 mm) guidewire through its guidewire lumen. This catheter comes packaged with a 0.035 in (0.89 mm), floppy tip guidewire preloaded in the guidewire lumen. The guidewire is 25 cm longer than the balloon catheter with the excess length extending from the hub end of the catheter.

A guidewire locking device is attached to the guidewire hub of the catheter. The locking device will be packaged in the "OFF" or unlocked position. The guidewire may only be advanced or removed from the catheter when the switch on the locking device is in the "OFF" position. The guidewire may be held in place within the catheter by moving the switch to the "ON" position.

5. Intended Use:

Indicated for use in adult and adolescent populations to endoscopically dilate strictures of the alimentary tract. The recommended application is printed on the package label referring to any combination of esophageal, pyloric and colonic dilatation.

6. Technological Characteristics:
The proposed CRE™ Balloon Dilatation Catheter is nearly identical in design, materials, and manufacturing processes to the predicate CRE™ Balloon Dilatation Catheter (K974788).

7. Performance Data:
In-vitro testing has been performed and all components, subassemblies, and/or full devices met the required specifications for the completed tests.

8. Conclusion:
Boston Scientific Corporation has demonstrated that the proposed CRE™ Balloon Dilatation Catheter is substantially equivalent to Boston Scientific Corporation's currently marketed CRE™ Balloon Dilatation Catheter (K974788).